

§ 810.18

(b) FDA may terminate a cease distribution and notification order issued under § 810.10 or a mandatory recall order issued under § 810.13 when the agency determines that the person named in the order:

(1) Has taken all reasonable efforts to ensure and to verify that all health professionals, device user facilities, consignees, and, where appropriate, individuals have been notified of the cease distribution and notification order, and to verify that they have been instructed to cease use of the device and to take other appropriate action; or

(2) Has removed the device from the market or has corrected the device so that use of the device would not cause serious, adverse health consequences or death.

(c) FDA will provide written notification to the person named in the order when a request for termination of a cease distribution and notification order or a mandatory recall order has been granted or denied. FDA will respond to a written request for termination of a cease distribution and notification or recall order within 30 working days of its receipt.

§ 810.18 Public notice.

The agency will make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new mandatory recall issued under § 810.13. The agency will delay public notification of orders when the agency determines that such notification may cause unnecessary and harmful anxiety in individuals and that initial consultation between individuals and their health professionals is essential.

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Subpart A—General Provisions

§ 812.1 Scope.

(a) The purpose of this part is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful